REMARKS

Reconsideration and withdrawal of the rejections are respectfully requested in view of the amendments and remarks herein.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 24-29, 31, 32 and 35-46 are under consideration in this application. Claims 24, 27, 29, 32 and 45 have been amended; claims 47-50 have been cancelled. Support for the amendments can be found throughout the specification.

No new matter is added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is expressly stated that these amendments are not narrowing amendments.

Sequence Listing

A new Sequence Listing is submitted herewith, and the specification has been amended to correct the sequence identifiers. The "new" Sequence Listing corresponds to the Sequence Listing originally filed with the application, and supercedes the Sequence Listings filed on December 18, 2000 and April 6, 2001.

A paper-copy of the Sequence Listing, and a computer readable form (floppy disk) of the Sequence Listing are enclosed. The Statements required by 37 C.F.R §1.821(f) and (g) are set forth below.

Pursuant to 37 C.F.R. §1.821 (f), the undersigned attorney hereby states that the content of the paper and computer readable copies of the Sequence Listing submitted in accordance with 37 C.F.R. §1.821 (c) and (e), respectively, are the same.

Pursuant to 37 C.F.R. §1.821 (g), the undersigned attorney of record hereby states that this submission, filed in accordance with 37 C.F.R. §1.821 (g), does not contain new matter.

In view of the amendments, remarks and enclosures, the application complies with the requirements for computer readable disclosure of the biological sequences under 37 C.F.R. §1.821-1.825.

II. THE REJECTIONS UNDER 35 U.S.C. §112, 2ND PARAGRAPH ARE OVERCOME

Claims 24, 27, 32, 42, 45, 47, 48, and claims depending from them were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

Claims 24 and 47 have been amended to recite --of--, rather than "shown under", as suggested by the Examiner.

Claim 27 has been amended to recite --comprising--, rather than "containing", as suggested by the Examiner.

Claim 32 has been amended to add --operably-- before "linked", and to recite --prokaryotic--, rather than "pro-".

Claims 47 and 48 have been cancelled.

The rejection of claim 42 is traversed. "Starch-storing plant" is a well-known term in the art of natural/agricultural sciences. Anyone of ordinary skill in the art knows that plants can be distinguished according to their main storage material, i.e. starch-storing plants or oil-storing plants. Examples of starch-storing plants are provided on page 12, lines 30-35.

The rejection of claim 45 is traversed. Claim 45 recites "propagation material", which is clearly defined on page 12, lines 37-39 of the specification. The Examiner is invited to review any of U.S. Patent Nos. 6,521,816, 6,483,010, 6,462,256, 6,353,154, 6,307,125, 6,307,124, 6,255,563, 6,255,561, 6,211,436, 6,207,880 and 6,162,966. The specifications of these patents contain a description of "propagation material" that is similar to that in the instant application, and all of these patents have issued with claims analogous to claim 45.

Reconsideration and withdrawal of the rejections under Section 112, second paragraph, are requested.

III. THE REJECTIONS UNDER 35 U.S.C. §112, 1ST PARAGRAPH, ARE OVERCOME

Claims 24-29, 31, 32, 35-50 and 53 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. It is assumed that claim 53 was inadvertently included in the rejections, as the Office Action states on page 2 that it is not under consideration. Claims 47-50 have been cancelled. The rejections with respect to the remaining claims are traversed.

The Office Action alleges on page 5 that "a wheat isoamylase protein has not been described by specific structural features or by specific function." This is simply untrue. The amino acid sequence of the protein is recited in claim 24, clearly providing a description of the

structure. Further, the recitation of molecules that hybridize to or have a degree of identity with the recited sequence(s) meets the requirements of §112, first paragraph. Further, the function of isoamylases, along with references describing isoamylases from maize and potato, can be found in the paragraph beginning on page 3, line 1. Briefly, isoamylases are debranching enzymes involved in starch synthesis and modification, and it is well within the abilities of the skilled artisan to perform routine enzyme activity assays to determine whether a protein encoded by a nucleic acid with, for example, 92% identity to SEQ ID NO:2 has the function of wheat isoamylase.

Enzo Biochem Inc. v. Gen-Probe Inc. (Fed. Cir. 01-1230; July 2002) holds that a functional description of genetic material may be sufficient to satisfy the written description requirement of 35 U.S.C. §112, since the requirement can be met by showing that invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, including functional characteristics, when coupled with known or disclosed correlation between function and structure.

Applicants have clearly provided relevant, identifying structural characteristics in the form of the nucleotide sequence of wheat isoamylase. Further, they have provided disclsoure in the application demonstrating the functional properties of the nucleic acid molecule and a correlation between function and structure. There are reasonable limits regarding what the claimed nucleic acid molecules can comprise. The fact that they are not necessarily required to comprise the exact disclosed sequence does not render them inadequately described.

Furthermore, limiting the Applicants to only the nucleotide sequence of SEQ ID NO:2 would unfairly narrow the scope of the invention. For example, other parties could use nucleic acid molecules distinct from SEQ ID NO:2 that encode a structurally and/or functionally identical enzyme to practice this very invention, and they would fall outside the literal scope of the claims. Such a consequence is obviously contrary to the intended function of the patenting system.

Claims 24-29, 31, 32, 35-50 and 53 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. It is assumed that claim 53 was inadvertently included in the rejections, as the Office Action states on page 2 that it is not under consideration. Claims 47-50 have been cancelled. The rejections with respect to the remaining claims are traversed.

Claim 24 has been amended such that part c) is limited to sequences that hybridize under stringent conditions with those stated under parts a) or b). The term "stringent conditions" is clearly defined in the section beginning on page 5, line 10 of the specification.

Examples 1 and 4 describe how to isolate and characterize cDNA molecules encoding wheat isoamylases. In addition, hybridization conditions are recited by the claims, and there is clear teaching regarding hybridization on page 5 of the application.

According to the Court of Appeals for the Federal Circuit in the case of *In re Wands*, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988),

> Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is undue, not experimentation. The determination of what constitutes undue experimentation in a given case requires the application of standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since **a considerable amount of experimentation is permissible, if it is merely routine**, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ... [Citations omitted].

Id. at 1404.

Against this background, determining whether undue experimentation is required to practice a claimed invention turns on weighing many factors summarized in *In re Wands* (*Id.*). For example, (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples of the invention; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.

With respect to the instant application, the amount of direction or guidance regarding how to isolate the claimed nucleic acid molecules is high, and working examples are clearly present. Although some experimentation may be necessary to determine whether a nucleic acid molecule isolated by protocols taught in the specification has the function of an isoamylase, the experimentation is routine. One of ordinary skill in the art knows how to isolate and analyze starch from a plant to determine the type and extent of its branching. The art of starch modification is well developed and the relative skill of those in the art is high.

It is submitted that claim 24 recites both structure and function, and that undue experimentation would not be required by one skilled in the art to reach a nucleic acid molecule covered by claim 24 or its dependent claims.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are requested.

IV. THE REJECTION UNDER 35 U.S.C. §102 IS OVERCOME

Claims 24-28, 31, 32, 35-42, 45 and 47-50 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Kossmann *et al.* The rejection is traversed.

Kossman *et al.* relates to a soluble starch synthase and a starch granule-bound starch synthase from potato, which are completely different enzymes than the wheat isoamylase of the instant invention. As these enzymes are not isoamylases, they will not hybridize with, nor do they have over 90% identity to the claimed nucleic acids.

Reconsideration and withdrawal of the rejection under Section 102 are requested.

V. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 24-28, 31, 32, 35-45 and 47-50 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kossman *et al.* taken with Vasil *et al.* Claims 24-28, 31, 32, 35-42 and 45-50 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kossman *et al.* taken with Baltensperger *et al.* The rejections will be addressed collectively and are traversed.

For reasons discussed above, Kossmann *et al.* do not teach or suggest nucleic acid molecules that would hybridize, under stringent conditions, to those of the present application. The enzymes of Kossman *et al.* are starch synthases, not debranching enzymes, are isolated from potato, not wheat.

Vasil *et al.* relates to a method for transforming wheat, however, the combination of references involving the transformation of wheat with a nucleic acid encoding a completely different enzyme from the current invention, would not result in the invention. Similarly, Baltensperger *et al.* claim a method for isolating starch from grain crops. In no way can Baltensperger *et al.* be combined with Kossmann *et al.* to arrive at the instant invention.

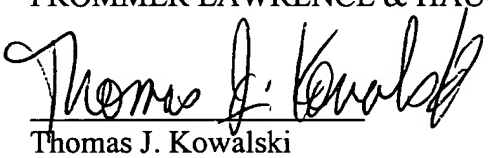
As the claimed invention is not taught or suggested by any of the cited references, alone or in combination, it cannot be obvious over them. Therefore, reconsideration and withdrawal of the rejections under Section 103 are requested.

CONCLUSION

In view of the remarks and amendments herewith, it is believed that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

On page 6, line 5:

Hybridization probes which can be used are, for example, nucleic acid molecules which have exactly ore essentially the nucleotide sequence stated under SEQ ID NOs:1, 2 or 6[SEQ ID NOs:1 or 3] or parts of these sequences. The fragments used as hybridization probes may also be synthetic fragments which have been prepared with the aid of the customary synthetic techniques whose sequence essentially agrees with that of a nucleic acid molecule according to the invention.

On page 30, line 6:

The DNA fragment employed as a probe for screening the wheat cDNA library was amplified with the following primers:

sulp-1: 5'-AAAGGCCCAATATTATCCTTTAGG-3' (SEQ ID NO:4)[(SEQ ID NO:5)]

sulp-2: 5'-GCCATTTCAACCGTTCTGAAGTCGGGAAGTC-3' (SEQ ID NO:5)[(SEQ ID NO:6)]

On page 31, line 28:

The insertion of clone TaSU-19 is 2997 bp in length and constitutes a partial cDNA. The nucleotide sequence is shown under SEQ ID NO:2[Seq ID No. 1]. A comparison with already published sequences revealed that the sequence shown under SEQ ID NO:2[SEQ ID NO:1] encompasses a coding region which has homologies to isoamylases from other organisms.

Sequence analysis also reveals that two introns are located in the cDNA sequence in position 297-396 (intron 1) and 1618-2144 (intron 2). If these introns are removed, a protein sequence may be derived which exhibits homologies to the protein sequences of isoamylases of other organisms. The amino acid sequence which corresponds to the coding regions of SEQ ID NO:2[SEQ ID NO:1] is shown under SEQ ID NO:3[SEQ ID NO:2].

On page 32, line 32:

The wheat-specific digoxygenin-labeled sugary probe employed for screening the cDNA library was prepared by means of PCR amplification. The primers employed in this reaction were:

SUSO1: 5'-GCT TTA CGG GTA CAG GTT CG-3' (SEQ ID NO:8)[(SEQ ID NO:7)], and

SUSO2: 5'-AAT TCC CCG TTT GTG AGC-3' (SEQ ID NO:9)[(SEQ ID NO:8)]

On page 33, line 32:

The nucleotide sequence of the cDNA insert in plasmid pTaSU8A was determined by means of the dideoxynucleotide method (SEQ ID NO:6)[(SEQ ID NO:3)].

The insertion of clone pTaSU8A is 2437 bp in length and constitutes a partial cDNA. A comparison with already published sequences reveals that the sequence shown under SEQ ID NO:6[Seq ID No. 6] comprises a coding region which has homologies to isoamylases from other organisms. Equally, the protein sequence derived from the coding region of clone pTaSU8A and shown in SEQ ID NO:7[SEQ ID NO:4] exhibits homologies to the protein sequences of isoamylases of other organisms. Upon comparison of the sequences of clones pTaSU19 (SEQ ID NO:1) and pTaSU8A (SEQ ID NO:6)[(SEQ ID NO:3)], a similarity of 96.8% results. Most of the differences regarding the sequences are in the 3'-untranslated region of the cDNAs. The remaining differences regarding the sequences in the coding region lead to different amine acids at a total of 12 positions of the derived protein sequences SEQ ID NOs:3 and 7[(SEQ ID NOs:2 and 4)]. The cDNAs contained in pTaSU19 and pTaSU8A are not identical and encode isoforms of the wheat isoamylase.

On page 34, line 28:

To clone pTa-alpha-SU8A, an approx. 2.2 kb portion of the TaSU8A cDNA, viz. positions 140-2304 of SEQ ID NO:6[SEQ ID NO:3] was amplified by means of PCR.

The primers employed in this reaction were:

SUEX3: 5'-GCG GTA CCT CTA GAA GGA GAT ATA CAT ATG GCG GAG GAC AGG TAC GCG CTC-3' SEQ ID NO:10[(SEQ ID NO:9)], and

SUEX4: 5'-GCT CGA GTC GAC TCA AAC ATC AGG GCG CAA TAC-3' SEQ ID NO:11[(SEQ ID NO:10)].

In the Claims

24. (Twice Amended) An isolated nucleic acid molecule encoding a protein with the function of a wheat isoamylase, selected from the group consisting of

(a) a nucleic acid molecule encoding a protein comprising the amino acid sequence of SEQ ID NO:3[shown under SEQ ID NO: 2],

(b) a nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:2[shown under SEQ ID NO: 1] or a part thereof or a ribonucleotide sequence corresponding hereto;

(c) a nucleic acid molecule which hybridizes under stringent conditions with a nucleic acid molecule mentioned under (a) or (b) or is complementary thereto, and

(d) a nucleic acid molecule whose nucleotide sequence deviates from the sequence of a nucleic acid molecule mentioned under (a), (b) or (c) owing to the degeneracy of the genetic code,

the nucleic acid molecule mentioned under (a), (c) and (d) having [a homology of] over 90% identity with SEQ ID NO:2[SEQ ID NO: 1].

27. (Twice Amended) The nucleic acid molecule as claimed in claim 24 comprising[containing] regulatory elements.

29. (Twice Amended) An isolated nucleic acid molecule which specifically hybridizes with the nucleic acid molecule as claimed in claim 24 and has a homology of over 90% with SEQ ID NO:2[SEQ ID NO: 1].

32. (Twice Amended) The vector as claimed in claim 31, wherein said nucleic acid molecule is operably linked in sense orientation to regulatory elements which ensure transcription and synthesis of a translatable RNA in prokaryotic[pro-] or eukaryotic cells.

45. (Twice Amended) Propagation[A propagation] material of the plant as claimed in claim 40.